



RON CHAPMAN, MD, MPH
Director

State of California—Health and Human Services Agency
California Department of Public Health



EDMUND G. BROWN JR.
Governor

April 3, 2013

Dear STD Colleagues:

I am writing to update you on a recent Food and Drug Administration announcement related to azithromycin safety.

Azithromycin safety and STD treatment in California

The U.S. Food and Drug Administration (FDA) issued an announcement on March 12, 2013, warning that azithromycin can cause cardiac arrhythmias. Patients at risk for these arrhythmias include those with known existing QT interval prolongation, low blood levels of potassium or magnesium, bradyarrhythmias (slower than normal heart rate), or those taking antiarrhythmic medications (e.g., quinidine, procainamide, amiodarone, sotalol). This announcement was based on an earlier study published in the New England Journal of Medicine (NEJM 2012; 366: 1881-1890) and a study conducted by Pfizer, the manufacturer of Zithromax. For more detailed information on the FDA warning, please go to <http://www.fda.gov/drugs/drugsafety/ucm341822.Htm>.

Importantly, the findings from these studies may not necessarily apply to the majority of patients who are treated with azithromycin for chlamydia or gonorrhea. First, the NEJM study population included patients ages 30-74 years, which is older than the majority of patients treated for chlamydia and gonorrhea in California. Second, the NEJM study examined the effects of a 5-day course of azithromycin, whereas the regimen recommended for chlamydia and for dual therapy for gonorrhea is a single dose regimen. It is unknown whether single-dose azithromycin regimens have similar effects on QT interval prolongation.

At this time, the Centers for Disease Control and Prevention (CDC) is recommending that treatment for chlamydia and gonorrhea remain the same as previously released in the CDC 2010 STD Treatment Guidelines. As a reminder, the recommended treatment for chlamydia continues to be azithromycin 1 g orally in a single dose, or doxycycline 100 mg orally twice a day for 7 days. The recommended treatment for gonorrhea is ceftriaxone 250 mg IM in a single dose plus either azithromycin 1 g orally in a single dose or doxycycline 100 mg orally twice a day for 7 days.

STD Controllers and Colleagues
April 3, 2013
Page 2

California health care providers who are treating chlamydia or gonorrhea in older patients with known cardiac disease have the option of using doxycycline 100 mg orally twice daily for 7 days instead of azithromycin. The California Department of Public Health STD Control Branch will monitor FDA and CDC alerts on azithromycin's safety profile and any recommendations related to clinical practice. We will notify you immediately if recommendations change.

If you have any questions, please do not hesitate to contact me at the phone number or email address below.

Sincerely,

A handwritten signature in black ink, appearing to read "Heidi M. Bauer", with a long, sweeping horizontal stroke at the end.

Heidi M. Bauer, M.D., M.S., M.P.H.
Chief, Sexually Transmitted Disease Control Branch
Division of Communicable Disease Control
Center for Infectious Diseases
California Department of Public Health
Phone: 510-620-3178
Email: heidi.bauer@cdph.ca.gov